

JFW



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April 5, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL OF SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/731,040 filed 12/8/2003  
Applicant: Steven W. Sanders et al.  
Title: COMPOSITIONS AND METHODS FOR MINIMIZING ADVERSE DRUG  
EXPERIENCES ASSOCIATED WITH OXYBUTYNIN  
Group Art Unit: 1614  
Attorney Docket No. T7770.CON4

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. §§ 1.56 and 1.97 is a Supplemental Information Disclosure Statement. Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

- ☒ Form **PTO/SB/08A AND PTO/SB/08B** list of 3 references submitted for consideration.
- ☐ Legible copies of the listed references or their relevant portions.
- ☒ Legible copies of the listed non-patent documents and foreign documents or their relevant portions are included.
- ☐ Copies of U.S. patents and/or publications are not included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i).
- ☐ All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

[www.tnw.com](http://www.tnw.com)

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The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

- ☐ Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.
- ☐ Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.
- ☐ Statement that certain listed references not enclosed were previously cited by or submitted to the Office in prior application no. \_\_\_\_\_, filed on \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- ☒ Statement under 37 C.F.R. § 1.97(e)(1) or (2).
- ☒ Check No. 24966, which includes the amount of \$180.00 (amount in § 1.17(p)) constituting the submission fee set forth in 37 C.F.R. § 1.17(p).

In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Statement meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 20-0100 of the undersigned.

Respectfully submitted,



David W. Osborne  
Attorney for Applicant  
Registration No. 44,989

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Sandy, Utah 84091-1219  
Telephone: (801) 566-6633

DWO/jmw

IN THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT: 1614

EXAMINER:

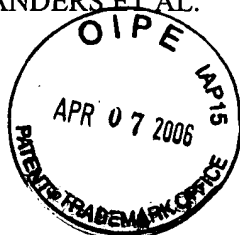
APPLICANT: STEVEN W. SANDERS ET AL.

SERIAL NO.: 10/731,040

FILED: 12/08/2003

CONFRM. NO.: 7563

FOR: COMPOSITIONS AND METHODS FOR  
MINIMIZING ADVERSE DRUG  
EXPERIENCES ASSOCIATED WITH  
OXYBUTYNIN THERAPY



**CERTIFICATE OF MAILING  
UNDER 37 C.F.R. § 1.8**

DATE OF DEPOSIT: 4-5-06

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Judy Wagner*

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form **PTO/SB/08A** and **PTO/SB/08B** which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

☐ 37 C.F.R. § 1.97 (b)(1) or (3), within three months of the filing date of the application, or before a first office action on the merits, whichever occurs last;

☐ 37 C.F.R. § 1.97 (c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in §1.17(p); or

☒ 37 C.F.R. § 1.97 (d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in §1.17(p).

While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that

the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☐ A legible copy of each listed U.S. Patent or publication (or relevant portion thereof) which was not previously submitted to, or cited by, the Patent Office is enclosed pursuant to 37 C.F.R. §§ 1.97 and 1.98.

☒ A legible copy of each of the listed non-patent literature and foreign documents or their relevant portions is enclosed.

☐ Copies of cited U.S. patents and/or publications are NOT enclosed pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. § 1.98(a)(2)(i).


☐ Copies of the references listed in the accompanying Form **PTO/SB/08A** and **PTO/SB/08B** are NOT enclosed because, under 37 C.F.R. § 1.98(d), they were previously cited by or submitted to the Office in application number \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.

Dated this 5 day of April, 2006.

Respectfully submitted,



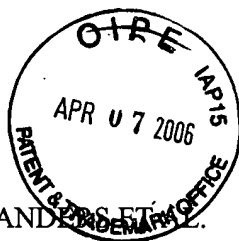
David W. Osborne  
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DWO/jmw  
Enclosure

IN THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT: 1614  
EXAMINER:  
APPLICANT: STEVEN W. SANDERS ET AL.  
SERIAL NO.: 10/731,040  
FILED: 12/8/2003  
CONFRM. NO.: 7563  
FOR: COMPOSITIONS AND METHODS  
FOR MINIMIZING ADVERSE  
DRUG EXPERIENCES  
ASSOCIATED WITH  
OXYBUTYNIN



<p><b>CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8</b></p> <p>DATE OF DEPOSIT: <u>4-5-06</u></p> <p>I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p><i>Judy Wagner</i></p>
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STATEMENT UNDER 37 C.F.R. § 1.97(e)

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form **PTO/SB/08A** and **PTO/SB/08B** which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

☒ I hereby certify that each item contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or;


☐ I hereby certify that no item contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information

contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

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Dated this 5 day of April, 2006.

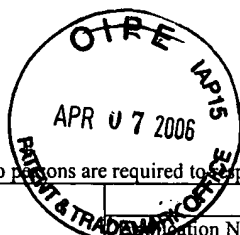
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DWO/jmw  
Enclosure



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Publication Number	10/731,040
		Filing Date	12/8/2003
		First Named Inventor	Steven W. Sanders
		Art Unit	1614
Sheet 1 of 1	Examiner Name		
		Attorney Docket Number	T7770.CON.4

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-			
		US-			
		US-			
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**FOREIGN PATENT DOCUMENTS**

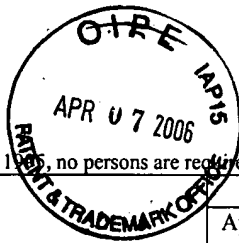
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 99/48493	09-30-1999	SCHWARZ PHARMA AG		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/731,040
Filing Date	12/8/2003
First Named Inventor	Steven W. Sanders
Art Unit	1614
Examiner Name	
Attorney Docket Number	T7770.CON4

Sheet	1	of	1
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BUYSE, GUNNAR ET AL., "Intravesical Oxybutynin for Neurogenic Bladder Dysfunction: Less Systemic Side Effects Due to Reduced first Pass Metabolism," The Journal of Urology, September 1998, pages 892-896, Vol. 160.	
		GUPTA, SUNEEL K. (PH.D) ET AL., "Pharmacokinetics of an Oral Once-a-Day Controlled-Release Oxybutynin Formulation Compared with Immediate-Release Oxybutynin," J. Clin. Pharmacol, 1999, pages 289-296, Vol. 39.	

Examiner Signature		Date Considered	
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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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